Clinical Operations Workgroup
Draft Transcript
January 25, 2011

Presentation

Judy Sparrow – Office of the National Coordinator – Executive Director
Good afternoon, everybody and welcome to the Standards Committee Clinical Operations Workgroup. This is a Federal Advisory Committee, so there will be opportunity at the end of the meeting, which will end about 3:00 for the public to make comment. Just a reminder for workgroup members to please identify yourselves when speaking.

Let me do a quick roll call. Jamie Ferguson?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Chris Chute? Martin Harris? Stan Huff?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Present.

Judy Sparrow – Office of the National Coordinator – Executive Director
Kevin Hutchison? Liz Johnson?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I'm here.

Judy Sparrow – Office of the National Coordinator – Executive Director
John Klimek? Wes Rishel? Nancy Orvis? Karen Trudel? Terrie Reed?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Jay Crowley?

Jay Crowley – FDA – Senior Advisor
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Chris Brancato?

Chris Brancato – Deloitte – Manager, Health Information Technology
Here.

Judy Sparrow – Office of the National Coordinator – Executive Director
Tim Cromwell or Nelson Hsing? Don Bechtel? Joyce Sensmeier? Ram Sriram? Did I leave anybody off? Okay, with that I'll turn it over to Jamie Ferguson.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Thank you, Judy and thanks, everyone, on the call. The purpose of today's call is to flesh out the agenda and the panel's questions and the purpose of our device interoperability hearing a little more than it has been to date. On our last call, we did talk about the overall purpose for the hearing being identification of barriers and enablers for device interoperability for a variety of use cases and a variety of care settings relative to meaningful use. We talked about setting up a series of six panels and I think everyone on the call should have gotten the brief write up of those six panels as we discussed them in our last meeting.

What I'd like to really focus on today is the why of the meeting, why are we doing this and be able to describe that a little better. Come up with a little bit of verbiage that we could help the potential panelists understand the purpose of the hearing so that we could have a good turnout and a good information sharing session. I'd also like to focus on who we might want to have in each of these six panels and see if we can identify names and contact and others who should be consulted in determining the shape of the panelists, the shape of the panels in terms of participation and individual names. Then, finally, and probably most of our time today I hope to spend on questions that we would write up and post to the panelists for them to consider and for panelists to respond to and these could be both questions that would go to all the panelists, we could have all the questions to all the panelists or we could have some focused more for some panels rather than others. So, I think I'd like to see how much we can flesh out those questions and get something down on paper so we can get out to some of the preliminary names of potential panelists that we identify on the call.

Now, for those on the call, does that agenda sound acceptable or do we want to modify that agenda for today?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I think that makes sense.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Anybody else? Any changes? Then, hearing none, let me just give a brief rundown of the six panels that we identified last time. What we agreed to was we would end up having six panels, four that are what I would call technical panels and a patient and provider panel, one each.

The patient panel: For that, we would seek to get input not so much from representative organizations, but from individuals who have had experiences and newer points of view and whose considerations we would want to take into account in terms of making sure that we maintain patient centeredness and focus for the individual consumer as an overall focus. So, I think hearing directly from individuals is important to that panel, but we also talked about having a provider panel and we talked about framing the day overall by having these two panels come first in the day.

In the provider panel, we talked about having providers who are familiar and experienced in the regulated device setting, primarily surgeons, anesthesiologists, folks of that nature, also having family docs, primary care or safety net types of generalists. We also talked about having nursing input on provider panel and particularly with reference to the amount of time that nurses have to spend basically transferring documentation into the EMR after reading it off of devices, but other input, certainly from nurses as well. So those were the first two panels that we talked about.

Now, is there anything that we want to potentially tweak or change about the nature of those panels?

Chris Brancato – Deloitte – Manager, Health Information Technology
Jamie, the only thing I would ask that we consider is someone from physical medicine and rehab.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, that's a good addition. I'm capturing notes as we go through. Then for the four technical panels—and we'll have an opportunity today to flesh out a little better the specific content of each of these—we talked about having one panel on interoperability and integration, primarily the transmission and data content standards. So we talked about their having, what I would call the usual suspects of

representatives from Continua and IHE and HL-7, potentially IEEE. I think those are certainly some of the main standards development organizations and we can consider other kinds of panelists for that technical panel.

We also talked about then having a panel on really data accuracy, talking about data validation, data integrity, providing trust in the data by providers and there we talked about having more of a mixed panel with providers, vendors and other kinds of participants and I think we'll have a chance to flesh that out a little more today. We also talked about having one panel that's focused purely on security, both data security at rest and in transmission as well as device security, physical and logical security of the devices themselves. There we talked about potentially having some of the security experts from the Healthcare Security Alliance, High Trust or others and I think we'll have plenty of opportunity to talk about the shape and participation in the security panel. Then, finally, we talked about having a panel here on unique device identification and so I think this certainly where we want to hear from the FDA and the National Library of Medicine, but also hear the vendor and provider and other viewpoints on device identification.

Those were the four technical panels that we agreed on last time and let me take input and comments from the group on how we might want to tweak and shape those.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Jamie, when you say vendors in this technical section, are you talking about EMR vendors or actually the manufacturers of the devices or both?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's a really great point, Stan, because I'm really talking about both. So, from the device standpoint, the big names come to mind right away, the Philips, GE, Medtronic, but I also think that we've talked certainly in the workgroup before about. In fact, the genesis of this hearing overall was some of the difficulties that providers have had in integrating device information into the EMR for use in clinical decisions, making clinical decision support. So, I think that we very much want to hear from the EMR vendors, so when I say vendors I mean in the biggest term and maybe we should be more specific about where we want to have device manufacturers or component vendors versus the software publishers in the EMR and clinical decision space.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, I think that might be a useful clarification and I agree that it would be important to hear from both.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, good. Other comments on these technical panels overall or any specific points on them before we move forward? I guess what I'm looking for is if there's some big chunk that we're missing or is there significant redundancy that we should deal with in these panels or does this sound about right?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
It seems about right to me.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I was thinking the same thing as you went through the explanation.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, well thank you both. So, this is the structure that we've agreed to. We've said that overall the purpose of the hearing is to identify barriers and enablers of device interoperability and interoperability requirements for a variety of use cases and a variety of care settings. How can we flesh out that description in a broader context?

I guess we have to be a little bit careful, certainly because we don't have a set of policy directions or requirements for meaningful use stages two and three yet, although we certainly have a proposal. We don't know completely what questions we need to be answering from a meaningful use perspective. At

the same time we think that this can inform that meaningful use discussion and determination of those directions.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Jamie, what you just said, because I just jotted off something, too. Do you have that documented somewhere because I think the objective you just espoused the appropriate objective. Are you thinking we need to tie it to our work as Standards Committee and more specifically to the potential need for additional standards? The hearing itself; I thought we were a fact-finding mission.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think it is a fact-finding mission. That's a good way to put it. I think it will support our work in the Standards Committee when standards are required, but I think also at the same time we already have requirements, for example, for recording vital signs and just in a very simple example, that's a function for rich device integration where the EMR can be very useful. So I think even within stage one of meaningful use there's room for what we discover to support the meaningful use program. Liz, tell me a little more about your thinking, if you don't mind.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Well, what I was thinking was what we're trying to do is determine, I think what are the perspectives from the panel. The two first panels are more like the end users and the operational challenges and the things that they're doing and the potential impact of what they need or what's really helpful or what have, so it's more setting the foundation. Then when you get into your technical panels, I think what we would be doing is then determining what standards are already there, how are they being utilized, are they standards that are simply sitting on a shelf gathering dust or have they actually been integrated into product development, are they required?

I think even the order you put these panels in, they build one upon the other, not completely; because I think from that then we can extract or determine where holes are, because I think the meaningful use piece of it that we all get is improving the quality of care. What our job specifically as the Standards Committee is more about if we get Paul and his group to put this into meaningful use stage three, for example, do we have work to do to make sure that those devices and our ability to talk to those devices from a Standards perspective is in place. You may know that, or Stan or others. I do not. I mean we are certainly dealing with these medical device companies, but we're dealing more round FDA than we are around, obviously, because there are no meaningful use standards. That's what I'm thinking.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think that's a really good perspective. I particularly like what you said, Liz, about identifying areas where standards are both more mature and less mature, if you will, to kind of paraphrase you, or, areas where having requirements put into meaningful use policy might be premature if the standards aren't there to support it.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Right, and we certainly have discovered that in the past. We certainly have identified a large body of standards that can be very clearly articulated to a specific requirement in the meaningful use. This is not a place that we've been with medical devices before.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. Now, do we want to have specific questions, when we get to tell you about the questions, just as a category, do we want to ask the panelists about the relationship of each of these areas to existing and proposed meaningful use requirements?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
We might be able to do that in the security area. Stan, what do you think? When I think about what we've got established in some of these other areas I'm not sure of the connection.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer

Yes. I'm not positive how it fits for meaningful use, but somewhere in the data accuracy and security, I think patient identification comes up and I'm not, go ahead, sorry.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Yes, can I ask a question about the scope of this in terms of is it just devices that talk to each other on a network or is it the realm of all devices, like implants, things like that?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think what we've talked about to this point, Terrie, is devices that I would say collect, record or transmit data that's used in the EMR, so not necessarily networks, but potentially ones that collect or manage data that are used in the EMR.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Okay. The reason I asked is because one of the things about UDI is that we were wanting to get into the EMR to be able to scan as you do with medication, scan the patient, scan the device for implants and things like that, so I just wanted to establish if that's inside this or no.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's a good point because, obviously, there may be information in the EMR about devices where the device doesn't produce data for the EMR.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right, the device associated with a patient, for quality, for recall, things like that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, I think that's not what we had originally envisioned, but that may be a very useful expansion in scope. What do others think?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I think I would probably tend to leave that out of scope for this discussion. That's my vote. I wouldn't feel bad if we included it either.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, well, let me ask you, Terrie, do you want that in or out?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Jay Crowley is on the phone, too.

Jay Crowley – FDA – Senior Advisor
We very much want that in scope. I think that's, from a device perspective, a much larger group of products and really, potentially, a much more important group of products than necessarily a non-invasive blood pressure monitor passing information. Though useful and appropriate, from a quality of care and patient safety perspective it's really a lot of other devices that we would be much more interested in their documentation in PHRs. I think that's a larger group and probably a potentially more useful group.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, but let me, I guess, push back or constrain that scope a little bit because since our charge is related to meaningful use and meaningful use is the use of the EHR technology specifically. I think we have to stay within the scope of the EHR technology as it's constructed in meaningful use. So, it would really be about the data that's in the EHR either that's provided by devices or it's about devices, but it wouldn't be really about the devices themselves unless they provided data to the EMR if that makes sense. Does that make sense?

Jay Crowley – FDA – Senior Advisor

I agree with that. No, I don't think we're suggesting that there should be anything other than, let's say that it's an orthopedic implant of some type that simply, you know, a recordation of that implant is what we were really talking about.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
That's why I brought up medication because it's the same notion of you associate medications with a particular patient, so you would associate what devices a particular patient has had or used.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, I think we're talking about two kinds of data here. One is about patient data, the actual data that comes from the device that then populates within the EMR and becomes part of the care record and the other is also in the record, but it's more of record-keeping. The orthopedic implant is a good example where we have to document within the patient care record anything that becomes part of their body during their episode of care. Are those the differentiations we're making?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, I would agree with that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I would kind of characterize that as two clusters of scope, if you will. One is the data that's about the devices that's in the patient record in the EHR and the other is basically data that's sent to the EHR from the device. That is an expansion in scope from what we had originally conceived of, but it sounds very useful. Are there any other comments on that?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I'm good with that. I think it makes sense. Especially in terms of patient safety, device recalls and other things. I mean I could well imagine some meaningful use thing that says, you know, medical devices, the identity of medical devices should be tracked in electronic medical records so that you can find out who needs to be notified if there's a recall.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Absolutely.

Jay Crowley – FDA – Senior Advisor
Right, exactly.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Good. So, I think that's a very good comment on the scope, thank you.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, from the panel perspective then, Jamie, is it possible that we may hear more from the provider panel about the type of information they would like to have available from devices? And from the patient perspective the type of information that they'd like to either provide to a device for purposes of dissemination of the information to care providers or because they've given warnings? When you talk about that sort of thing and when you get into technical panels, tell me how this data discussion plays in.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, because it seems to me that in terms of the technical panels— I think what we're saying is that a lot of this discussion about the data, about the devices, particularly the implanted devices, would really be in that last—what I've currently labeled as panel number six. Whereas the other three would be primarily about the data that's sent to the EHR from the devices and how that works and how it's managed.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics

Right. So, we may want a unique question for that last group that talks about meeting the requirements of reporting, recalling and so on that might be different.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think that sounds right. Does that also sound right to others?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
On a different subject, Jamie, again, an issue that occurs to me in the interoperability and integration—and here I need to disclose, again, my role as a co-chair of LOINC. But one of the issues that we've been promoting and talking about is the fact that the ideal way for a lot of this integration to work is that people who have devices assign LOINC codes. Because they're the people who know exactly what their device is measuring and producing so that you don't have the situation where you buy the device and then you try and figure out what LOINC code that measurement corresponds to and people could do it different and other things. But you actually, at the manufacture as part of the instrument documentation or the device documentation say, we measure blood pressure and blood pressures measured by this device should be assigned this LOINC code for purposes of transmission in an HL-7 message or an observation message. So, it might be worthwhile to have Clem or somebody else—actually the National Library of Medicine has been involved in trying to promote that as well, so that might be another one in that panel number three that might be an interesting topic to introduce.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, well I wonder and if that's really about panel number three or if it's really part of more the UDI discussion in panel number six? It's another aptitude of UDI in other words.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, I could go with either classification. That would be fine.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I was writing notes, Jamie. I was thinking the same thing. I thought what Stan was describing would go under unique identification. It may need to come out. Are you asking, Stan, if the Standards Group needs to push that? We need to find out what Standards are doing about it and we need to find out what the Unique Device Identification bodies are also doing. What does FDA say about that? So, it's kind of both.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I mean at a minimum we'd like to get it understood as sort of a best practice in the industry and if I had my way I would probably actually move toward regulation in that area, but that's my personal.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, Jay and Terrie, how do you feel about having the discussion about LOINC, either in the messaging panel or the UDI panel?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
I'm fine with it being in the UDI panel. I think, wasn't this brought up at HL-7 STL meetings, the addition of LOINC codes?

Jay Crowley – FDA – Senior Advisor
Probably. I wasn't in that particular session, but it's certainly come up there before.

Terrie Reed – FDA/CDRH – Associate Director for Informatics

One of our requirements for UDI submissions will be HL-7 SPL and I think that was brought up from FDA in part, not our particular office, but the In Vitro Diagnostic Office. So, it sits there I think. The number three and the UDI, they're going to have close connections because we're using standards, too. We're using HL-7 message and using GS1.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Hi, this is Nancy Orvis from DoD. I've just joined. I apologize for being late today.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Hi, Nancy. Welcome. Nancy, we're talking about some of the issues and questions that we would want to bring up in the different technical panels as well as the patient and provider panels that we agreed to on our last call. In particular, we also agreed to suspend the scope of the hearings, so it's not just about data that's provided or sent to the EHR by or from devices. But it's also information or data about the devices that's in the EHRs, that's in the information bout implanted devices, in particular, that are part of this patient record and how those are useful and maybe used in potentially meaningful use.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think that's extremely important. I was just talking with someone this morning because we have a representative, a medical materials manager on the GS1 Committee and it's the product metadata with the FDA meets…, that's another piece of that. We've been talking about getting a publishing guide for product metadata on devices so that at point of implantation or attachment to people a lot of that metadata can go in the record, such as the serial number of the device, date of manufacture in case of recall, unique identification of what it is and how it will now be kind of like fill out your customer consumer warranty card. You need to have that put in the record as well.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right. So, what we're saying is that most of that discussion will happen in what we're now calling panel six, just the Unique Device Identifier, but there will also be some of that discussion in panel three, which is more about the interoperability and integration messaging and how those things are represented, for example, in HL-7 messaging.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Great. Now, when is panel three scheduled for and when is panel six, because that will help you; part of the things is also figuring out who are the people to invite to these right?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, that's one of the other things we want to get to today. So, what I wanted to do today is have this overall discussion on why we're doing it and we're leading into some of the questions, specific questions for the different panels. Then I also want to get to who we would consider inviting and see if we can wrap up by confirming some of the questions that we had proposed for some of the different panels to answer. So, the way it's structured right now, to Nancy's point, is that we have the patient and provider panel first to kick off the day. This is structured as a one day hearing, it may be a long day. We wanted to fit it into one day and it is scheduled for March 28th. So, we wanted to have the patient and provider panel first and then the set of four technical panels.

The way it's set right now—and we can certainly change the order—is that the interoperability and integration panel with the messaging and, basically, the device information standards for information to the EHR, panel three is the first one up. Then we have the panel on data accuracy validation, data integrity, that's a provide trusted data. Then after that, we have security, which is both data security and device security and then we have the unique device identification panel being last. Is there a desire to change that order?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Two is the interoperability and then three is the device, the actual data feeds from the device itself, the patient data?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
The first two, the first two panels, panels one and two, are to hear from individual patients and individual providers about their experience, their viewpoints. So, these would be patients who either want information or have had issues with information about devices, either in their medical record or would like to have, for example, their home vitals or their home chronic measurements entered into the EHR for the physicians, that sort of thing.

Then, on the provider panel, we talked about having individuals from both the surgical and anesthesiologist, operating setting, then also having some family docs, primary care providers, nurses and rehab or physical medicine providers as well.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Would that include some people on chronic care diseases, too?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think so. I think that was the idea for the patient panel.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Yes, you'd certainly want chronic disease management under that, just rehab for the diabetics or the breathing or the other issues, COPDs, whatever.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think that order; and then panel four, data accuracy; five, data security and possible tagging of data, is there where something?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Now, what do you mean by tagging of data? Tell me about that.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Well, one of the things that I've been looking at and thinking about with the PCAST Report is being able to tie security to the data element level and part of data security is not only just the creation of it, the transport of it and whether you're protecting it from violation. It could be SAMHSA type data, you know, alcohol, drug; how do you tag the history of alcohol drug abuse treatment or HIV status or something else that's a secure, however you want to tag it.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, and I can give you an operational twist on it, Jamie. One of the things that our doctors are asking is they want to know where the data came from because they want to decide whether they're going to act on it from a clinical perspective.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, no I think that was really one of the main points about our data accuracy and validation data integrity idea and maybe those two panels should.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think data accuracy is the right place to say you can't look at data without knowing who was the patient and you have to feel secure that it's really that patient. You have to be really secure that it's from an accurate data source. So, to me that is one of the key pieces of data accuracy. Can you trust it from that perspective? That's not necessarily a security issue, but is it trusted data that you know that if it comes from this you're going to give it the accuracy tag.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, what I'm getting from this is that we would add the metadata tagging of the nature that's in the PCAST Report to the data accuracy and data integrity panel.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

Or data security; I thought the tagging was from, well, there were two aspects of it, but the other one was security.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Are you talking there in terms of security privacy?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
A perfect example is HIV status. In my internal systems for years, the only person who could see the HIV result was the doctor who ordered it. Nobody else got to see the result of an HIV status on any patient, even if they're looking. The SAMHSA, the mental and drug abuse has this issue of it's not allowed to be forwarded unless the patient gives another consent. One doctor can't forward drug/alcohol information to another doctor without the express consent of the patient. So, that's kind of sort of a security tag. This is a do not forward set of data unless you have a consent key to unlock it.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, we go full circle back to medical devices, in terms of the panel, Nancy, Jamie, others, are we anticipating then the download of that type of data from a medical device directly into the EHR?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
That's the plan that my material managers and I, we were talking about the vendor community on materials management system would love to take metadata from a product manufacturer and stick that in there because they have device recall software. Patient safety issues, and that really help that, but the true benefit would be, say, in a pre-op setting where certain devices, or in a pharmaceutical prescription where certain medical devices are issued out to a patient.

You would be able to put that metadata about the device from their structured product label, which is what the FDA has to go out and put this and get manufacturers to agree to do, it should be able to be sucked right into that person's record. So, you'd have the point of origin, the date of manufacture or the Unique ID number for that particular device, etc.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
All the junk we're writing on paper right now.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes, and your use case for this is the next Hurricane Katrina; somebody goes and loses all their equipment in a flood, they've got to go somewhere else; not only implanted devices, but what are assistive electronic devices, okay? It's your inhaler or the things asthmatics use to do their nightly inhaling stuff. You've got to replace all that equipment. I was interested in not only electronic; I mean, medical devices covers everything from electronic to non-electronic and I think, Jamie, weren't you scoping this to be pretty much electronic medical devices?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, no. I think the point about the expansion in scope is that while originally we had scoped it as being about devices that provide data or measurements that are used in the EHR. I think what we agreed to here is that we wanted to have the data and metadata about the devices that's in the EHR that's part of the patient record for tracking the non-electronic devices as part of the tier record.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
And there can be implanted devices and non-implanted devices because it includes the titanium hips or the stents, it could include metal plates in heads. Now durable medical equipment is where assistive devices go, like canes and artificial limbs. That's considered a DME. Do we want to have the whole scope from the DME categories to the implanted and non-implanted devices?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Well, it's important to say that's a question more for the UDI panel to consider, isn't it, in terms of scope? I don't know. I guess, Jay and Terrie, how do you two feel about that? Do we really care about the particular things that were used in the exam room? Does that have to be in the record?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
We're going to have a UDI on all regulated medical devices, what's captured in the electronic medical records probably left to that UDI group and to the provider and patient care panels to see what information, what devices they're most interested in.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I know I would be interested in my perspective from the tri-care insurance that devices that are prescribed or implanted or become part of the patient's continuing care and that includes for me durable medical equipment and/or whether it's a diabetic with certain things or whatever, because those could be recalled, too. Or whether it's an artificial limb and it also includes on the other side implanted devices or other medical devices that transmit information, so I guess it could be animate and inanimate, things that transmit and don't transmit.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
I mean, I've talked to hospitals that want to track catheter use, for example, for quality of care and when the catheter is implanted, when it's explanted, be able to track that via the electronic medical record, so even something like a catheter.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Well, that's all supplies used, that are inserted in a patient. You could track the sponges going in and out, too, that way.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
So, it wouldn't have to be a permanent implant.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I would say the data about the device, we would certainly be interested that there becomes a universal set of metadata for medical devices, not just medications and then there is the other aspect of that, which is data transmission for medical devices.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and what I was going to say was that we're really concerned, I think, not just with the transmission, but also devices that record data that's used in the EHR that don't today transmit where it has to be re-transcribed and re-entered manually.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
So, we need to get clearer recording devices or something, medical data recording devices.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think devices that transmit or record data that's used in the EHR as well as what you said, Nancy, about devices that are prescribed.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I said medical device product data, medical device product information metadata and then the other one, as you said, is medical device transmittal or recording data.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, so the FDA defines it as medical devices, products used for medical purposes in patients, diagnoses, therapy or surgery. Then I think what you've done is then taken it further delineated two categories; those that transmit data, that have metadata tagging and those that we need then to put information into the record itself. Otherwise, Jamie, we're going to boil the ocean.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, that's not the intent. I think this is useful. Now, does that scope in terms of those two areas, both the product metadata and what I'll call really the device data, or data from devices, is that clear to everybody on the call? Is that a clear, sort of well-bounded scope for us?

Chris Brancato – Deloitte – Manager, Health Information Technology
Yes, I agree with that definition, rather than trying to stratify devices in contest for us, such as DME because there are plenty of devices in the DME category that meet the definition of being able to capture and record oximeters and BiPAP, CPAP machines, ventilators, that kind of stuff.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, Chris, are you saying those are in or out, like a ventilator?

Chris Brancato – Deloitte – Manager, Health Information Technology
No, they should be in. As it is we don't put them in the category of assigning them to DME, while they are DME and can be DME. I like your definition better, Nancy. It's functionally based and I think that's more appropriate.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
What comes to mind for me is that as we've been talking about this sort of one category really is the device product metadata, the product data and the other is what I'll call the interoperability data, which is sort of our original scope, which is the information that's transmitted or recorded.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
But you know, okay, I would say there's an interoperability issue, too, if you have patient safety on product data. It's like think of medication safety, if you didn't have the produce info in your record, wouldn't you be a patient safety issue?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Yes, that's what I was mentioning earlier, it's very similar.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
The goal is you want to uniquely identify everything used because my practical goal is in three years or so I'd like to have a patient summary list where somebody had a list of not only their problems and their medications and their labs, but what were their implanted devices and their other assistive devices they need to live? That's really what I want to have is that I want to have a list and let's say it's a wounded warrior, somebody with chronic conditions. I'd like to be able to have a summary list. What does this person need to function in society with, all these assistive devices and what's implanted in them so I know not to run them through an MRI.

You know, pacemaker; well, the other issue we're getting to on that is shrapnel precautions for anything with a magnetic metal in your body. That's a sidebar, but additionally, from a chronic disease perspective I would think that those categories and there would be device recording data. I think there are three different needs here. One is how do you get the recording data into the records so you can do something with it, that's absolutely critical.

But it's also important, I think, for chronic care and for lifelong healthcare that there's a medication summary of device, a patient device summary, implanted and otherwise, and assistive. But if the point will be to fundamentally get the data transmissions stuff first, I would be happy with that as long as we address the product metadata because I think these hearings this year will help get the international sections of the GS1 and help the FDA get its request for metadata submissions out and get accepted by manufacturers. Because as I understand it the FDA can't do this; well, they've got to put out a request for submission.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Well, we can regulate that.

Jay Crowley – FDA – Senior Advisor
We are regulating that.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
We'd more like to have adoption on the healthcare provider side and we don't regulate that.

Jay Crowley – FDA – Senior Advisor
We'll take care of the device manufactures. Don't worry about that.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Okay, fine. Need to get it in the record then.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Let me switch gears a little bit because although we've gone fairly deep into the different aspects of the discussion around device identification, the need for it, the different aspects of product metadata, let's go back to the ideas and some of the questions around basically how to get the recording data into the EHR, some of those interoperability questions. But also do we want to go into the scope of how they're used? So, for example do we want to ask questions about whether products are suitable for wireless applications unless they're used only in a carefully engineered wireless network zone?

So, there are just so many different questions about the practical interoperability of how to get the data into the EHR. What is in the minds of those on the call, what are some of the most important questions to be asking?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
One of the things that occurred to me is that we could at least prompt people to think about the environment where it's being used. Because I think there are probably some different issues in the home versus things in an inpatient environment and there might even be two inpatient environments, a regular four-bed, if you will, and then the ICU. And just to get people to think some things are probably the same, but other things might be quite different and to get them to think sort of specifically and when they make comments, whether their comment pertains to sort of all devices or when you're using the device in the home or when you're hooked up to one in the hospital.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, let's just explore that thread a little bit, Stan. So, in terms of thinking about the use of devices in different settings, what are some of the questions that we would want to tease out? I mean, do we want to talk about the, do we want to elicit answers rather, do we want to ask questions that would get to the boundary between what an FDA regulated or regulatable product is?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, I mean in some sense it's sort of the same issues that we've sort of been talking about with device identification and that sort of stuff, if I were a patient at home, just imagining, you know, you want it to really be plug and play or even no plug and play, Wi-Fi. The idea would be that the assumption is you have a user there who may not, you hope they don't have to know anything about LOINC codes or anything else and, in fact, that depending on what you talk about it comes into this security and validity and confidentiality.

How do we know securely that it's hooked up to the right person? How do we know the identity of the person that it's hooked to and is that something that has usability issues around it? I think it's a little different to think about that in the home versus where you assume either in a clinic or a hospital that you've got more people that you can ask that might be more expert in the use of the equipment than when they're at home. I may be just thinking about things that aren't pertinent, but it seems like when you talk about validity, identity, all of those things, it has a little different flavor in the home than it has if I'm assuming that I'm in the hospital and have trained professionals that are working with it.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
No, I think your point is well taken, Stan. It does go fully back to integrity that data is coming over, how can the clinician that's interpreting or even the patient, but a clinician who may be receiving the data be assured that the data they're receiving is on the same patient they think they're receiving it from. It's a great point and I don't have any idea what the plans are around that kind of.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
One of the thoughts I have is when digital cameras first came up, you buy a camera from a store, they give you this piece of software and say you can upload your pictures to our Website and we'll develop them for you or whatever, you know, Ritz Camera. I'm thinking is that something we want to talk about where doctors prescribe certain kinds of devices and there is a standard set of software interfaces so that no matter what kind of data it is, there is an adapter to say here's your insulin reader stuff, here's your oximeter adapter. There's a common adapter that can go into; the device manufacturers would create a common adapter to allow it to go into a record, because, again, that's the same idea. The consumer doesn't need to know how your picture goes up to Ritz Camera or Cannon Camera or wherever it is or help it; they just want to stick the thing from their camera or the little cord from their end of their PC and send it up.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think, Nancy, that's an interesting question. One the things that seems to me is different is that a lot of the devices that we're talking about that record or transmit data, they're used or useful to different patients at different points in time, so the sort of the relationship of a device to a patient is not immutable. I think that's true certainly in the home environment where if it's a Smartscale or a blood pressure cuff, you know, that's going to be used by everybody in the home, but it's also a visiting nurse taking a device from patient to patient.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Gee, that would kind of preclude the idea that patients would have a Unique Identifier card, don't you think that they'd scan in first and then you put the data in because that's the only other way you do that. You put something that's like a universal patient identifier that then allows you to send the next data coming that's related to that patient.

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I was thinking of implanted RFID.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I was, too.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I would agree. Your dog and cat have one in their neck.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I'm sure our patients wouldn't be as thrilled, but I would feel like we were a lot safer.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes, aren't there a consideration of proposal for hearings finally again for the national patient identifier?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, it keeps coming up, doesn't it?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, I think, Stan, you originally brought up the importance of patient ID and I think this is just really emphasizing that. It seems to me that questions about patient ID generally and its importance could be applicable to potentially all of the panels, right?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief

I think this gets very critical. It's this whole data accuracy. You can have accurate data from a machine, but if you don't know who it's on, big deal. You've lost three of the key aspects, you know the patient, you know the provider and you know the data. But, I think that's going to be kind of key coming up here. I mean, in a controlled environment like an inpatient or a skilled nursing facility or anything where there's licensed care providers doing the intake and they have ways to hook that up to the right patient and it's going into a closed system, that's a different case. I believe there's easier control there because if you're in an inpatient or a nursing skill facility you already have some kind of patient ID within that facility.

So, maybe that's an easier tack to take and say homecare device is going to be problematic without a way to uniquely identify the person. It's just a thought, but, Stan, wouldn't you agree there's slightly more control and validating of the person's identity in any kind of controlled care setting?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
Yes, no, I think that's right.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Yes. Now, the homecare setting is going to be very difficult without a patient identifier issue, either issued by the healthcare organization or something. I can see us with a different little key tag on our key chains from every doctor we got to in the United States. I love it, six or seven of them for people that don't belong to Kaiser or some other closed system. That's really what we would want to look at precluding, too.

Chris Brancato – Deloitte – Manager, Health Information Technology
Another category that I'm thinking here, I'm just sort of thinking out loud, one things that we could ask folks—I think, Jamie, it extends the question you asked, should we ask them about meaningful use. I guess thinking about that I'm thinking, you know, if you ask them for the kind of devices that you produce or use, what are the patient safety issues? What are the things that we could do to improve quality of care? I'm thinking specifically at Intermountain, Scott Evans has done some very interesting work for doing automatically alerting when people disconnect from their ventilator. So, as you think about the devices, it would be interesting to get testimony from them and say sort of what can go wrong. And what would be either quality or patient safety issues that you can think of about the device that we might want to consider for meaningful use and best practice and improved quality that the device might provide.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
So, say we could ask it on both sides, both of the providers and of the manufacturers themselves, the vendors, right?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, certainly you're talking about the patient safety and quality issues that are relating to meaningful use on the regulated devices, but what about for the homecare devices or I'm just going to say iPhone apps and things of that nature? Is there a way to identify some of the risk patterns and should we try to explore that in this hearing?

Chris Brancato – Deloitte – Manager, Health Information Technology
Well, I'm not sure where you're going with that, but what jumped into my head is that if we did this right, we could almost have like a total weight sum at the end of every day because people could just enter in their daily weight in their iPhone. We would have a running average for the country of people's weights, to see how we're doing on obesity. Or, exercise minutes; there are some public health sort of.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
So, you think of biomass gained per second; the ecologists would love it. The country is getting heavier by the second.

Chris Brancato – Deloitte – Manager, Health Information Technology
That may be too weird to think, even for this environment.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I could see the bio-ecologist, wow, we would know total biomass and then we would look at all the carbon gases emitted by the biomass and say.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Sorry, we are getting a little odd on that one.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
It's not even happy hour and here we are.

Chris Brancato – Deloitte – Manager, Health Information Technology
Yes, and I already have an application on my iPhone that does exactly what you say. It uploads it into my PHR.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
And I guess part of where I was going with that line of questioning about some of the risks of homecare devices was, perhaps, aimed more at the security panel in terms of—well, I guess both security and data accuracy and validation—in terms of issues by encryption and having an objective means of knowing the original source of the data, tracking it back via some mechanisms, whether it's a digital signature or some other mechanism. To me, those are some of the important issues in terms of the use of bringing those kinds of live data into the EHR is both knowing that it wasn't tampered with or that it wasn't altered in transit, but also that it's authentic data. That it's accurate from whatever the source is, that it's known to the user of the information. I guess that doesn't turn people on.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Where do you want to go with it?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I think you described exactly the kind of information we're looking for, Jamie.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
It's so perfect that we're just.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, we're just sitting here absorbing it.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Can you put that on an iPhone app? Do we think there are some questions that these vendors or providers are really trying? I mean, there is one aspect, like you said, if a person just wants to record it and get it into their own personal health record and then take it to their doctor for monitoring, I guess that's the question. I don't know how well connected that stuff is to actual healthcare organizations. I'm sure all the providers are interested in it, but is there a way that once you put it in your own personal health record, well, you send that via secure message with a question to your doc?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I mean from the perspective of the organization where I work, we're always trying to get more information directly from patients, but that doesn't mean that it should be in the medical record, right?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Right, you don't want to glut it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So I think there is, certainly in my experience, some naïveté on the part of some of the homecare device industry and some of the promoters of PHR in thinking this automatically is to be used by a provider, by a physician in making a care decision without understanding that it has to go through some validation and attestation and so forth.

Chris Brancato – Deloitte – Manager, Health Information Technology
I absolutely agree with that, Jamie. Whether it's electronic or not, we face that issue now where patients show up with a five inch binder with all of their medical information and expect you to look through it all.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes. So, what's the right way to attack that line of questioning in terms of questions for the panels? Maybe it's to try to get the panels to identify both differences and similarities.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
How would they actually then transmit? And what were their thoughts of devices that transmitted directly into a patient collected set of documentation and the ways to make copies of that to send to provider organizations? Is that what you mean by similarities and differences?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I think that's a good way of putting it, sort of differences and similarities of patient collected data versus provider collected data and what the requirements are for both?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Right. And I don't know, that analogy that I have is, you know, it's like people take lots and lots of their own pictures, but they only want to upload a couple of them and send them to all their friends. It's kind of sort of the same idea. If you're going to be wanting devices that allow you to collect it, but then you can select and upload to give to your doctor.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I would circle back, Jamie, to the second panel and ask the providers what they want and maybe even ask the patients what they think. It's interesting, Chris' analogy of the people that come in with the binder of information and the brown sack of medications. Those are very real things in hospital and doctor's offices every day.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Sure, and when you're doing medication reconciliation.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Absolutely.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Actually, that's an interesting question. How would this data affect; I mean there are meaningful use in medication reconciliation.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, there are.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
And one of the key things you need is trough and peak levels on certain kinds of things. Some of these devices help you indicate is the medication working as directed, is the blood pressure going down, is the sugar level going up or down?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Well, that even goes back to the simple example that was given earlier about your weight. It was a different context, but it's the same thing. Is your diuretic working?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
Is your diuretic working, right. Is your glaucoma medicine working, is whatever it is working and part of medication reconciliation would then be adjustment of the doses; not directly, but it would be the secondary piece out of that. But there could be a question about that, what kind of ties would they like to

see between that and the medications? You also want that patient to record when they started taking St. John's Wort or something else or the 1-800-Dietpill.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, it seems to me that what we're sort of circling around is perhaps a more general question of how would data from devices affect the measures that are related to stage one? Really something about the stage one measures.

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I like that.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, I think that's a good line of questioning. Do we want to ask specifically, so staying on the meaningful use track do we want to ask analysts to address what information relative to devices should either be explicitly in or out of stages two or three? Do we want to go there or is that really out of scope for us?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Jamie, when we did our hearings we couldn't avoid it. It came up anyway. People are already looking at what is being proposed for two in detail and then sort of that glimmer on three, so it may come up. The vendors may ask you. It's kind of like what several of us have been talking through the process of this conversation. There are some of us who would probably like to see some of that to help move the industry along.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
I know that FDA definitely wants to have some.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
What are any major areas of questioning that we have not addressed yet? Actually, it's kind of a refreshing conversation for me because we did not really focus on things that have circled around in the past about some of sort of the core messaging standards for interoperability and questions about where to use IHE versus continuous classifications where some of the IEEE standards should apply and so forth.

We have a panel that's sort of devoted to that area and maybe that's pretty well contained in that. Okay, let me ask, maybe related to my last point, but it's a slightly different line of questioning, which is about networks devices and both wired and wireless networks. What are some of the questions about the network connectivity of devices that we might want to explore here because, again, sometimes there are assumptions about ubiquitous availability of networks and things like that that don't sort of pan out in the operational reality?

Nancy Orvis – U.S. Department of Defense (Health Affairs) – Chief
I think that's a good point because you can drive 50 miles from Washington and still lose connectivity in the hills. I think that's a question of, it certainly is a real healthcare issue, could be, that you can't assume wireless is everywhere; remote monitoring in the remote sense. So, are you looking to ask those guys about questions like that, is that what you're saying, Jamie?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Well, that's my question to the group here is what sorts of questions about the kinds of networking connectivity issues, what do we want to ask?

Chris Brancato – Deloitte – Manager, Health Information Technology
Jamie, just to spur some thought, would it be fair game for us to ask then are they supporting network enabled devices now? Because there are plenty of devices in use today that are not network-enabled, but they do have the ability to transmit data either over the telephone or some localized network. But we're talking, based on the example, we're talking about network Web-enabled WAN kind of devices? Okay.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, I think it's a good question. Are you supporting network-enabled devices today? Do you support the Web WAN connectivity or other transmission methods? Okay. So, I'm going to try to switch gears with this call a little bit. We've got about a half an hour left and then we've got to leave some room for public comment at the end. So, we've talked about sort of the why of the hearing, we talked about scope, in terms of both the private information and the devices, the data that's either recorded or transmitted from the devices. We've talked about, I've got about a page and a half of notes from our discussion about potential questions, but let's talk a little bit about who.

Now, we did talk about this a little bit on the last call and the notes that were sent out in preparation for this call included some of those, so let's start back with the patient and provider panels. Again, in the patient panel we talked about having individual patients that have some either particular experience or viewpoints so that we could get a range of input from the patient's perspective. We talked there about both experience with implanted devices, experience with homecare devices as well as chronic care patients who want to regularly get information to their care team. What else do we need to talk about in terms of seeking individual patients for the patient panel?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Jamie, I think that sort of description will get us the kind of persons that we need and I didn't catch whether you said that we'd try to go local, if possible, to avoid the travel issues?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, I think that's a good idea.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Because we know these persons are not ones that travel easily.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, exactly. Okay. Let's move on then to the provider panel. So, we had talked about from an inpatient hospital setting having a surgeon and anesthesiologist. We also talked about having primary care providers, family doctors who are involved in chronic care on their panel. We also talked about nurses, particularly about the issue with security to get input on the issue of transcribing information from devices into the EHR and what the set of requirements are there. We also talked about rehab and long-term care settings. So, that's a pretty full list for the provider panel.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, the only caveat that I'd add in it, if we select persons that we could try to look at sort of a diversity of types of persons. In other words, not everybody from a large academic or a small rural because sometimes as you start to give off names of people you know they come from particular settings and we don't get a full sense of the environment. But it needs to be someone that can speak to it. If you're in a setting that's not even fluent in this sort of work yet you may have concepts, but you may have a difficult time really adding to the testimony. You've got a good list.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
So, I think that's a good point so we'll look for sort of a mix of panelists there from large and small organizations, from urban and rural environments, from academic centers, but also potential from safety net or essential tier centers. Then to just move on to continue characterizing the panels, for the interoperability and integration panel we really talked primarily about the standards development organizations here. We also talked about asking FDA to contribute to this discussion. Who else belongs on that panel? Is that the right way to characterize this? Do we need vendors or providers there, too? What's really needed for that panel?

Terrie Reed – FDA/CDRH – Associate Director for Informatics

I think FDA is a good choice because there are groups working on it within FDA, but also have you considered the CIOs or the IT folks at the healthcare providers? Those are the people that would have to implement these systems. Are they part of this?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's a great idea. Okay, so implementers being some of the IT directors of provider organizations.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right, there's also biomedical engineers. AAMI is a good group, American Association of Medical Instrumentation. They have a lot of biomedical engineering members.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. Good, so I've got that in the notes as well. In terms of the data accuracy and validation, we talked just very broadly about having providers and vendors there, but not any more specific ideas. When we talked about the provider panel it's a very long list of different kinds of providers and so maybe some of those can really come here to this panel four and give requirements on what the provider/user requirements are for data accuracy and integrity and so forth. What do folks think about that idea?

Chris Brancato – Deloitte – Manager, Health Information Technology
I was thinking a vendor could go panel three and four because there are vendors working on devices, network devices that you put in a home where your devices can essentially plug and play and upload data, as Stan described before. I think some of those are the same people that have to speak to accuracy validation and integrity.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, it really kind of bleeds over, if you will, from panels three, four and five. It's hard to completely distinguish those issues. So, let me just throw out an idea, a potential restructuring idea for consideration. What if the sense of questions for panels three, four and five were combined and instead we have panels sort of by participant type. So, we have a panel on that whole set of questions from the standards perspective, another one from vendors, another one from providers. Does that make sense or is it better to focus panel discussion the way we have it now on a narrower set of questions from a broader spectrum?

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I like the perspective of what they're going to talk about rather than the type of person they are because I think you may find your panel going to a certain subject and then you'll miss all the rest of the content that you want specific to the four subjects that were identified, interoperability data, and you get it.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Right, okay. No, I just wanted to test that because I think what Chris was pointing out was just like earlier we talked about there being sort of bleed over from panel four to panel five, there's also a lot of bleed over from panel three to panel four.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, and I think he's absolutely right and I think you will get some of it no matter what you do, but at least we could try to keep them focused on the subject at hand.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So, let me just ask a little more pointedly because I think from the other panels we have some ideas about who would participate, but who would be some of the main kinds of organizations participating in panel four, either individuals or organizations?

Stan Huff – Intermountain Healthcare – Chief Medical Informatics Officer
I hesitate to volunteer without asking them, but there are people within Intermountain that would have probably some interesting things to say there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and I was thinking the same thing from a Kaiser standpoint, but I didn't want to fess up to it.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
But if you guys have that kind of knowledge that can be shared, I understand the hesitancy to bring in your own organizations, but it's a good source of information for the hearing panel.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, so let me see, do we have a VA person on this call? But I know, Nancy, obviously, from the defense standpoint, but between VA and DoD we may want to ask for some what I'll call government provider input on this as well.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, and I think particularly considering the types of persons that they are having to deal with this in the MedITAC bay and so on. It's a good idea.

Nelson Hsing – Veterans Health Administration – Management Analyst
Yes, this is Nelson Hsing from the VA and I'm listening and so, yes, I thought VA probably have some use cases I can share with the group.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, Nelson, thank you. I forgot you were on the call. I'm sorry.

Nelson Hsing – Veterans Health Administration – Management Analyst
Oh, that's okay. I didn't announce.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Are there vendors in this area that those of us on the call have used and think bringing legitimate information to the panel?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
I don't know if there's a specific focus on this area.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I'm drawing the same blank and I thought maybe others had used somebody or at least to talk to somebody in this area.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, but I think certainly … is participation. So, let's move on to security. Now, in security some folks mentioned there's the High Trust organization that has established sort of a private sector set of modeled security controls and I don't know if that really covers device data or not, quite honestly. I know there's the Health Security Alliance, which is a provider and vendor alliance for the most part.

Another idea that came to me was I know that the ISO Technical Committee 215 is looking at the IEC or that risk framework and risk management process for device security, in particular. It seemed to me it might be useful to get, I know Todd Cooper wears a lot of hats, but I think he's the chair of that work group in ISO working on that. It may be useful to get the ISO perspective on that. Who else, well, if folks agree with that and then who else would be useful on this panel?

Don Bechtel – Siemens Medical – IT Architect, Standards & Regulatory Mgr.
You might want to tap into somebody like AVIMED, they're a medical device group, so a lot of the vendors are participants there that might be able to participate in this. There's also a group called MIDA, which might actually be associated with AVIMED, I'm not sure.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
I was looking at the Continua Health Alliance to see if there was anything there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and so we have Continua slated currently for panel three, messaging interoperability.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Oh, yes, I see that, I'm sorry.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
That's not to say that we can't have organizations on more than one.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Right. That was just the one— I was digging through my contacts looking to see who we've talked to.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
One of the things, when I was thinking about this I was thinking more about getting statements of requirements in terms of what is needed for security, but maybe we really need to, as I think Don and others were saying, get some of the practitioners, some of the manufacturers and others who are really creating and providing solutions into the marketplace to see sort of what's being done, as opposed to more of a focus on the requirement. So, balance between what's needed and what's being done.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
Yes, I think that's more, the sense of what you get from that is more balanced, I think you're right.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. I'll move on then, I think that's sort of a half a dozen ideas for that panel. Let's move on to panel six then in terms of the UDI and let me turn this part of the conversation over, I guess, to Jay and Terrie first to ask what would be most useful and most productive from your standpoint?

Terrie Reed – FDA/CDRH – Associate Director for Informatics
I think Jay left the call at 2:30, so in terms of the participants who would be the most productive I would say there are folks in the supply chain, so the standards groups associated with that. So, again, you're kind of back to HL-7, GS1, similar groups that you're going to get with interoperability.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, and we had also talked about potentially having LOINC on that panel and representatives from the National Library of Medicine.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right and FDA. We're actually trying to set up some sort of a public meeting as well on UDI, so we're kind of brainstorming on the same kind of thing, who would be people to invite to that meeting. We're in the middle of that process so I could get back with you on specifics.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay, because, obviously we don't want to duplicate that.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right, but I mean that's a different kind of a thing; it's more just share the word about UDI. This is, I think you're trying to get at feedback on specific questions from these folks.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, and also this is more directly related to EHR technology in the context of meaningful use.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
Right. So I would also say, well, you have the HR vendors, right?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy

Right.

Terrie Reed – FDA/CDRH – Associate Director for Informatics
There are EHR vendors, we were talking about today the fact that there are many systems in the hospital that would feed to EHR or that would integrate on device information for like recall data and that kind of thing, so there are clinical systems, not just the HR, but I know you're focused on that. You may just want to invite the EHR folks for now.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Yes, okay, good. Okay, well that's good. So, I've got another page of notes now from our discussion on potential panelists or at least types of panelists, not necessarily individuals for the first two, but I think we'll have a chance to come back to that and to seek input. So, if anyone in the workgroup has specific individuals they want to have considered for being invited onto these panels, please send that in to Judy Sparrow and to me and John Halamka, who couldn't make this call, but is our co-chair of this workgroup.

Then I think unless there is other business to conduct, I think we've covered what we set out for this call. So, let me ask if there is anything else folks want to bring up, either on what we've discussed or anything else that could be brought before the workgroup.

Elizabeth Johnson – Tenet Healthcare – VP Applied Clinical Informatics
No, you made a lot of progress, though. I think we're going to get there.

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
Okay. So then, I think, Judy, we're ready for any public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, great. Operator, can you please check with the public and see if anybody wishes to make a comment.

Moderator
We already have two public comments.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay, go ahead please. If you'd identify yourself.

Alan Hobbs
I have actually some supportive statements basically to the implant device identification. I'm associating that to EHR. I think that's important. I think Jay and Terrie and Nancy addressed that. Also I recommend the mapping of device ID and the patient ID, I think Stan addressed that as well and also recommend exploring the use of the device as it's related to wellness and preventing chronic illnesses and that could be done, I believe, Jamie, with the patient panel as well as panel three with continuing their track on wellness. Then the last comment is on the use of the mobile device and ancillary capabilities; will the mobile device at some point at some point be a regulated class of (inaudible)? That was it.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. Hobbs. And we have another comment.

Joyce Sensmeier – HIMSS – VP of Informatics
Hi, this is Joyce Sensmeier. I'm on the workgroup, but for some reason I was muted during the call I believe. Just wanted to suggest, Jamie, a consideration on the patient panel, the number one. Should we insert the word consumer there because, certainly the Continua work is around a lot of the devices in the home and the chronic care. Some of those folks may be considered consumers rather than patients at any given point. I don't know, it's just something I wanted to put out there in case you get questions about that later.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Thank you, Joyce.

Moderator
We do have another comment from the public.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay. Go ahead, please.

Sara Coulter – Philips Healthcare – Director, Global HIT Policy and Industry Relations
Hello, this is Sara Coulter from Philips Healthcare and we'd be honored to testify and share any information we have with regard to devices and electronic health record in both the home environment as well as the hospital. Additionally, we're very strong members of Continua and we'd be most happy to participate. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, very kind. If you want to send me your e-mail address that would be wonderful and we'll just keep it on record.

Sara Coulter – Philips Healthcare – Director, Global HIT Policy and Industry Relations
Very good, thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Any other comments? Okay, Jamie, back to you.

Moderator
We do actually have one more that just joined in.

Judy Sparrow – Office of the National Coordinator – Executive Director
Okay.

Jim Hansen – Dossia Consortium – Vice President and Executive Director
Hi, good afternoon. This is Jim Hansen, Dossia Consortium. I just wanted to reiterate a couple of things that were said earlier and make sure that the workgroup considers devices that are not limited to directly providing data to the EHR, but also devices that are used for self-management in the home setting and come in either through the PHR or home health. And that a summary of that is then presented into the EHR and also connecting back to meaningful use stage three, which has an integration of the PHR into EHR. It's important to understand that remote monitoring and wellness and other types of data with scales and vital signs will be coming in through that mechanism and I think it's important to add that to the process. Thank you.

Judy Sparrow – Office of the National Coordinator – Executive Director
Thank you, Mr. Hansen. Jamie, any last comments?

Jamie Ferguson – Kaiser Permanente – Executive Director HIT Strategy & Policy
No, I think that's it. Great comments. Thank you, everyone and I look forward to our next call.

Judy Sparrow – Office of the National Coordinator – Executive Director
Great. Thanks, Jamie.

Public Comment Received During the Meeting

1. Comment - Please consider devices that are not limited to directly providing data to the EHR but also devices that are used for self-management and captured in PHRs and then a summary is forwarded to the EHR. Meaningful Use stage 3 includes integration of PHR to EHR which will include remote monitoring data from devices.

2. Thank you - An additional couple points to add to this: 1) remote monitoring data (e.g. diabetes) is needed by many providers within the care team, frequently not in the same organization, 2) with an increasing focus on wellness, physicians (especially primary care) will want to check in to see patient data (vitals/exercise/nutrition in a virtual visit) at various time checkpoints between face to face visits.

3. As a member of the public without a conflict of interest, Kaiser, InterMountain and VA/DoD are great sources for testimony and should not be passed up because they are represented on this WG